

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H-33301A	FOR FURTHER ACTION	See Form PCT/PEA/416
International application No. PCT/EP2004/008538	International filing date (day/month/year) 29.07.2004	Priority date (day/month/year) 30.07.2003
International Patent Classification (IPC) or national classification and IPC A23K1/18, A23K1/17, A23K1/00, A23K1/16, A61K9/00		
Applicant NOVARTIS AG		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 27.05.2005	Date of completion of this report 06.10.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Rooney, K Telephone No. +31 70 340-	



**INTERNATIONAL PRELIMINARY REPORT
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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements* of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-39 as originally filed

Claims, Numbers

1-64 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
 4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
- * If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 33-35, 64

because:

☒ the said international application, or the said claims Nos. 33-35, 64 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-64
	No: Claims	
Inventive step (IS)	Yes: Claims	1-64
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-32,36-63
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

For the assessment of the present claims 33-35 and 64 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Re Item V.

1 The following documents are referred to in this communication:

D1: EP-A-1 247 456 (PFIZER PROD INC) 9 October 2002 (2002-10-09)

D2: GB-A-2 300 103 (GILBERTSON & PAGE ;HARRIS ROGER CHARLES (GB)) 30 October 1996 (1996-10-30)

2 Independent Claims

The subject-matter of claim 1 meets the requirements of Article 52 (1) with respect to the available prior art. The document D1 discloses palatable veterinary compositions comprising veterinary drugs (e.g. amebicides), meat flavouring, glycol softener and less than 5% water. The compositions may also contain pre-gelatinised starch (see D1; page 5, line 41-44; page 6, paragraph 3; page 7, lines 19 and 25-28 and example 1). The subject-matter of claim 1 differs from the teaching of the document D1 in that partially gelatinised starch is used in the composition. The effect of this difference is that the product may be produced by cold extrusion. The objective problem of this application therefore is provision of palatable veterinary compositions comprising veterinary drugs wherein the composition retains an affective amount of pharmaceutical activity (see description page 5, par. 2 - page 7 par. 2). The document D2 discloses a palatable composition for companion animals comprising partially gelatinised starch and creatine (see D2; page 2, par. 2 - 6, claims 1 and 15). However, this document while addressing the problem of destruction of the active ingredient, does not provide a

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means of cold extrusion. Rather the extrusion occurs at the relatively high temperatures up to 130°C. Furthermore, creatine is a nutritional supplement, as opposed to a veterinary ingredient where exact dosages and activity retention are more important. Consequently, the teaching of D2 does not solve the problem of the application and it is deemed to have an inventive step. Independent claims 30 and 36 comprise the subject-matter of claim 1 and therefore also comply with Article 52 (1) PCT.

3 Dependent Claims

The subject-matter of claims 2-29, 31, 32 and 37-63 satisfy the PCT with respect to novelty and inventive step by virtue of dependency on claims 1, 30 and 36.